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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER			SWITZER, JULIET CAROLINE		
LLP 901 NEW YORK AVENUE, NW			ART UNIT	PAPER NUMBER	
WASHINGTON, DC 20001-4413			1634		
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Please find below and/or attached an Office communication concerning this application or proceeding.

		App	lication No.	Applicant(s)			
			979,558	MARUYAMA ET AL.			
	Office Action Summary	Exa	miner	Art Unit			
			et C. Switzer	1634			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
THE - External effect of the control of the contr	ORTENED STATUTORY PERIOD FO MAILING DATE OF THIS COMMUNIC assions of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this communic period for reply specified above is less than thirty (30) operiod for reply is specified above, the maximum state are to reply within the set or extended period for reply were ply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b).	CATION. f 37 CFR 1.136(a). I nication. days, a reply within drory period will apply ill, by statute, cause	n no event, however, may a reply be ting the statutory minimum of thirty (30) day y and will expire SIX (6) MONTHS from the application to become ABANDONE	mely filed ys will be considered timely. n the mailing date of this communication. ED (35 U.S.C. § 133).			
Status							
1)⊠	1)⊠ Responsive to communication(s) filed on <u>08 March 2004 and 21 September 2004</u> .						
2a)□	<u> </u>						
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposit	ion of Claims						
5)⊠	, <u> </u>						
Applicat	ion Papers						
9)[The specification is objected to by the	Examiner.					
10)	☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)	Replacement drawing sheet(s) including the oath or declaration is objected to			• , ,			
Priority (ander 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
Attachmen	t(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)							
3) 🛛 Infori	e of Draftsperson's Patent Drawing Review (PT mation Disclosure Statement(s) (PTO-1449 or F r No(s)/Mail Date <u>6/2004</u> .	O-948) TO/SB/08)	Paper No(s)/Mail D 5) Notice of Informal 6) Other: See Continu	Patent Application (PTO-152)			

Continuation of Attachment(s) 6). Other: sequence alignment 1 and sequence alignment 2.

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DETAILED ACTION

1. The examiner handling this application has changed. Please address all future correspondence to Examiner Juliet Switzer, Art Unit 1634.

2. This action is written in response to applicant's correspondence submitted 3/8/04 and 9/21/04. Claims 1, 2, 3, 4, 5, 6, and 7 have been amended and claims 10-18 have been added. Claims 1-18 are pending, claims 8-9 are drawn to a non-elected invention. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Applicant's remarks are addressed following the statement of the rejections. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 2, 3, 4, 5, 6, 7, and 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims each recite or depend from a claim that recites "wherein the part of the base sequence of SEQ ID NO: 1 is a region specific to the Psychrobacter pacificensis NIBH P2K6 strain." However, the specification fails to recite what is meant for a region to be "specific" to a particular strain. The specification demonstrates that the embodiment recited in claim 3, that is SEQ ID NO: 3, succeeded in the species specific detection of P. pacificensis and P. glacincola,

office action, in the interest of compact prosecution.

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detecting four strains of P. pacificensis in addition to the NIBH P2K6 strain (Example 4) and teach that the region of SEQ ID NO: 2 is "specific" to the bacterium (p. 11). In light of the fact that the specification teaches and exemplifies that this "specific" sequence hybridizes to a number of organisms (4 strains and one additional species) other than P. pacificensis, it is not clear what it means for a sequence to be "specific" to the recited strain. Thus, in light of these teachings, it is not clear if specific means, for example unique to this strain, or if it is intended to have a broader meaning, for example meaning any subsequence of SEQ ID NO: 1 that would hybridize to P. pacificensis strain NIBH P2K18 in a Watson-Crick base pairing specific manner. Applicant's arguments in the response imply the former interpretation, but the teachings of the specification do not appear to support this interpretation, and so it is unclear what applicant

Claim 4 further illustrates this confusion because the probe appears to recite conflicting requirements, first requiring that the claimed probe be "specific" to P. pacificensis strain NIBH P2K18, but later reciting an intended use for the probe of alternatively identifying P. glacincola. Thus, in light of these two requirements, it is confusing as to what it means for the probe to be "specific" to the strain. Claim 5 is likewise confusing because it recites alternatively identifying P. glacincola but requires that a probe comprising a part of SEQ ID NO: 1 specific to alternatively identifying P. glacincola is used in the hybridization.

means by the use of "specific" in this claim. Both possible interpretations are addressed in this

Claim 5 is further indefinite because it is not clear how the two obtaining steps are related. That is, it is not clear if applicant's recitation of "obtaining the purified 16S rDNA of Psychrobacer pacificensis" is intended to mean that first the 16S rDNA is obtained, for example

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from P. pacifensis.

as the target DNA for detecting or identifying, or if this is meant to be an obtaining so that in the next step "obtaining a purified oligonucleotide probe comprising part of the base sequence of SEQ ID NO: 1" is to be accomplished by isolating the probe from the obtained 16S rDNA. If applicant intends the latter, than it is not clear in the final step what the probe is permitted to hybridize to. If applicant intends the former (i.e. that the obtained P. pacifiensis is meant to be a target for probe hybridization) then it is not clear how this method can be used to accomplish the set forth goal of detecting Psychrobacter glacincola since the sample is specifically required to be

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Claim 6 is further indefinite because it is not clear how the two obtaining steps are related. That is, it is not clear if applicant's recitation of "obtaining the purified 16S rDNA of Psychrobacer pacificensis" is intended to mean that first the 16S rDNA is obtained, for example as the target DNA for detecting or identifying, or if this is meant to be an obtaining so that in the next step "obtaining a purified oligonucleotide probe comprising part of the base sequence of SEQ ID NO: 1" is to be accomplished by isolating the probe from the obtained 16S rDNA. If applicant intends the latter, than it is not clear in the final step what the probe is permitted to hybridize to.

Claim Rejections - 35 USC § 112

- 5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 6. Claims 2-7 and 10-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising instant SEQ ID NO:

1, wherein the nucleic acid is specific to the Psychrobacter pacificensis NIBH P2K6, does not reasonably provide enablement for oligonucleotides comprising fragments of instant SEO ID NO: 1 wherein the oligonucleotides are specific to the Psychrobacter pacificensis NIBH P2K6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejected claims are also rejected this office action for being indefinite. This rejection is written against a potential interpretation of "specific" which means that the claimed oligonucleotides must be "unique to" and/or would detect only the recited Psychrobacter strain. This is one possible interpretation of the claims. A broader interpretation is addressed in the art rejections.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (MPEP 2164.01(a)).

Claims 2, 4, 6, 10, 11, and 12 are drawn to oligonucleotide probes that comprise any "part of the base sequence of SEQ ID NO: 1, wherein the part of the base sequence of SEQ ID NO: 1 is a region specific to the Psychrobacter pacificensis NIBH P2K6 strain." Claims 5, 7,

and 13-18 are drawn to methods in which such a probe is employed in "detecting or identifying at least one bacterium selected from" *P. pacificensis*, *P. glacincola*, (claim 5) or in "specifically detecting or identifying a bacterium belonging to" *P. pacificensis* (claim 7). These claims further require that the "part of the base sequence of SEQ ID NO: 1 is a region specific to the Psychrobacter pacificensis NIBH P2K6 strain."

The specification teaches instant SEQ ID NO: 1 which is disclosed as being the 16s rRNA gene from Psychrobacter pacificensis strain NIBH P2K6 (p. 2, lines 15-16). This sequence is 1526 base pairs in length. Instant SEQ ID NO: 1 in its entirety appears to be unique to Psychrobacter pacificensis strain NIBH P2K6 based on a sequence search of the art. The most closely related sequence identified was from P. pacificensis strain NIBH P2K18 (see enclosed sequence search results). The specification further teaches instant SEQ ID NO: 2, which is a fragment of SEQ ID NO: 1 and which is demonstrated in the specification as succeeding in the species specific detection of P. pacificensis and P. glacincola, detecting four strains of P. pacificensis in addition to the NIBH P2K6 strain (Example 4). Example 5 demonstrates that under high stringency conditions that do not allow for mismatches, instant SEQ ID NO: 2 hybridizes to all five strains of P. pacificensis, but not the tested P. glacincola sample. The specification does not exemplify a single fragment of instant SEQ ID NO: 1 which is unique to the P. pacificensis NIBH P2K6 strain.

In order to determine which portions of instant SEQ ID NO: 1 would be "unique" to this strain, one must be able to compare instant SEQ ID NO: 1 to the 16S rDNA sequence from closely related species of organisms. In the instant specification no guidance is given as to the sequence of this gene form other Psychrobacter species. At the time the invention was made, the

closes prior art over the full length SEQ ID NO: 1 was the 16s ribosomal RNA gene partial sequence from P. glacincola as disclosed in GenBank record U85876 which had 87% identity over the full length SEQ ID NO: 1 and 95.9% local identity when nucleotides 30-1498 of SEQ ID NO: 1 were compared to nucleotides 12-1481 of the record (see enclosed Sequence Alignment (1)). This sequence has a mismatch with instant SEQ ID NO: 2. However, the prior art also teaches a different fragment of the P. glacincola 16S rDNA in GenBank record AF025555, and this record comprises SEQ ID NO: 2 in its entirety. The entire fragment taught in this second record shares 99% identity with nucleotides 210-508 of instant SEQ ID NO: 1, differing only by the insertion of a single nucleotide over the full length sequence (see enclosed Sequence Alignment (2)). Thus, though the P. glacinola sample tested in the specification was not detected under high stringency conditions, the P. glacinola sample used to obtain the nucleic acid disclosed in this record would be detected by instant SEQ ID NO: 2. Thus, even applicant's most preferred oligonucleotide would not be expected to be "specific" to the specific strain recited in the claims, nor even to the entire species. The sequence of the 16S rDNA genes of additional strains of P. pacificensis were not known in the prior art at the time of filing of the instant invention.

It is unpredictable as to whether one of skill in the art could make and use applicants' invention in a manner reasonably commensurate with the instant claims. The specification exemplifies the successful use of a single subsequence of SEQ ID NO: 1, SEQ ID NO: 2, in the detection (as well as the differentiation) of P. pacificensis and P. glacincola (see entire specification, particularly Examples 3-5). However, as discussed previously, instant SEQ ID NO: 2 is also disclosed in the prior art as being within at least strain MED12 of P. glacincola,

and thus SEQ ID NO: 2 would be expected to detect this strain as well. The specification does not, however, provide a single sequence that would differentiate strain P2K6 from other strains, and indeed the post-filing date art demonstrates that this sequence is with at least strains P2K18 and P2J13 (see GenBank records AB016059 (nucleotides 472-454) and AB016056 (nucleotides 473-455)). The instant claims are sufficiently broad so as to encompass probes comprising any subsequence of any length selected form SEQ ID NO: 1 that is "specific" to P. pacificensis strain NIBH P2K18 and the use of any such probe in the detection of not only P. pacificensis and/or P. glacincola. The specification only exemplifies the successful detection of two particular species (P. pacificensis and P. glacincola) with a single species of probe (SEQ ID NO: 2). The specification does not identify or provide guidance for the identification of any nucleic acid fragment of instant SEQ ID NO: 1 that is specific (i.e. unique) to P. pacificensis strain NIBH P2K6. Lacking guidance from the specification, one of skill in the art may look to the teachings of the prior art for further guidance and enablement of a claimed invention. In the instant case, the prior art as exemplified by Bowman et al (Applied and Environmental Microbiology 63(8):3068-3078 [8/1997]) teaches the use of a universal primer sharing regions of identify with SEQ ID NO: 1 in detection of P. glacincola, but does not begin to provide the sequences of the 16S rDNA gene from closely related strains of P. pacificensis that would be necessary for comparison in order to determine the regions of SEQ ID NO: 1 that are "specific" to P. pacificensis strain NIBH P2K18. Neither the teachings of the specification nor of the art enable the identification or use of the of probes encompassed by the claims in identification of P. pacificensis, P. glacincola wherein "specific" to the strain means that the sequence is unique to or would hybridize to only the strain recited in the claims. Further, in this interpretation, the

specification does not provide any discussion as to how such a probe (even if it were identified) would be used to detect P. glacincola when it is "specific" for only one particular strain of P. pacificensis. While it is clearly within the ability of one of skill in the art to conduct further experimentation aimed at identifying additional subsequences of SEQ ID NO: 1 that may be useful in specific identification of P. pacificensis and/or P. glacincola (and possibly other species considered to be analogs thereof), the outcome of such experimentation cannot be predicted, and more specifically, which of the subsequences of SEQ ID NO: 1 that are "specific" to the individual strain P2K6 are entirely unpredictable. Accordingly, it is unpredictable as to whether any quantity of experimentation would result in the identification of any other species that may actually be used successfully in the methods disclosed by applicants.

There can be no doubt from the teachings of the specification that applicant could have made any possible fragment of SEQ ID NO: 1, given the full length nucleotide sequence of this molecule, using standard molecular biology techniques at the time the invention was made. However, given the teachings of the specification, and the exemplification that SEQ ID NO: 2 hybridizes to at least five bacterial samples other than P. pacificensis NIBH P2K6, and that instant SEQ ID NO: 2 is disclosed as being within P. glacincola strain MED12 DNA, it is entirely unpredictable which of those fragments would be "specific" to P. pacificensis NIBH P2K6 wherein "specific" is interpreted to mean that recited oligonucleotide is unique to or would hybridize only to nucleic acids from this strain. Applicant has not given a single example of a fragment of SEQ ID NO: 1 that would meet this requirement. Accordingly, with respect to the requirement that the probes claimed and used in the methods recited herein comprise a part of SEQ ID NO: 1 that is specific to P. pacificensis NIBH P2K6, and insofar as this requirement is

intended to mean that the probes are unique to or would hybridize only to this strain, it would require undue experimentation to make and use applicants' invention in a manner reasonably commensurate with the instant claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 2, 3, 4, 6, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinhassi et al. (GenBank Accession AF025555, GI: 2582456, dated 02 November 1997).

Pinhassi et al. teach an isolated nucleic acid comprising part of the base sequence of SEQ ID NO: 1. Namely, the isolated nucleic acid taught by Pinhassi et al. shares 99% identity with nucleotides 210-508 of instant SEQ ID NO: 1, differing only by a single insertion of a "c" at nucleotide 122 of the sequence taught by Pinhassi et al. relative to instant SEQ ID NO: 1 (see attached alignment entitled "Blast 2 Sequences results"). Nucleotides 250-268 of the oligonucleotide taught by Pinhassi et al. are the complement of SEQ ID NO: 2 and to nucleotides 458-476 of SEQ ID NO: 1 (Nucleotides 458-476 of SEQ ID NO: 1 are identical to SEQ ID NO: 2).

Thus, with regard to claim 2, Pinhassi et al. teach a purified oligonucleotide probe which comprises part of the base sequence of SEQ ID NO: 1, wherein the part of the base sequence of SEQ ID NO: 1 is a region "specific" to the Psychrobacter pacificensis NIBH P2K6 strain. With

regard to the final "wherein" clause of this claim, it is noted that the specification does not provide a definition of what it means for a region to be "specific" to a particular strain. Further, the exemplified embodiment of such a sequence in the specification, and in the claims is instant SEQ ID NO: 2. The sequence taught by Pinhassi et al. comprises instant SEQ ID NO: 2, and thus clearly meets this limitation of the claims.

As noted, with regard to claim 3, the sequence taught by Pinhassi et al. comprises instant SEQ ID NO: 2.

With regard to claim 4 and claim 6, the sequence is from P. glacinocola and shares 99% identity with nucleotides 210-508 of instant SEQ ID NO: 1 from P. pacificensis.

With regard to claim 10, the probe comprises nucleotides 458-476 of SEQ ID NO: 1, as previously discussed.

Thus, the teachings of Pinhassi et al. anticipate the claimed invention.

9. Claims 2, 4, 6, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Maruyama et al (Marine Biology 128:705-711 [1997])("Maruyama et al-1").

Maruyama et al-1 disclose the universal 16S rRNA primer, 27f (see page 707, left column). It is an inherent property of this primer that it is a probe comprising "part of the base sequence of SEQ ID NO: 1" (for example, nucleotides 5-11 and 13-17 are identical to nucleotides 1-7 and 9-13 of SEQ ID NO: 1, respectively). Regarding claims 4 and 6, it is further noted that the recitation in the claims of an intended use for the claimed products (specifically, the recitation in claim 4 "for detecting...analogs thereof" and in claim 6 "for specifically detecting....*Psychrobacter pacificensis*") does not result in a structural difference between the

claimed invention and the molecule taught by Maruyama et al-1, and further that the molecule of Maruyama et al-1 is capable of performing the intended uses recited in the instant claims. (See MPEP 2111.02 for a further discussion of the weight given to statements reciting purpose or intended use of a claimed product). With regard to claims 11 and 12, the primer is 20 nucleotides in length. Regarding the newly added limitation that the part of the base sequence of SEQ ID NO: 1 "is a region specific to the Psychrobacter pacificensis NIBH P2K6 strain," it is noted that the specification does not provide any definition of what it means for a region to be "specific" to the strain. The only example of such a region is given in instant SEQ ID NO: 2 which is also within the 16S gene of P. glacincola (see specification p. 21, lines 11-13), and thus, the term "specific" as used in the claims is broadly interpreted to mean that the region would specifically hybridize in a base pair specific manner with a portion of the Psychrobacter pacificensis NIBH P2K6 strain. Both nucleotides 5-11 and 13-17 of the primer taught by Maruyama et al-1 would be expected to hybridize to this strain since they are identical to portions of it, and thus the primer "comprises" part of the base sequence of SEQ ID NO: 1 that is

Accordingly, Maruyama et al-1 anticipate claims 2, 4, 6, 11, and 12.

a region specific to the Psychrobacter pacificensis NIBH P2K6 strain.

Response to Remarks

The objections to the claims and the 101 rejections are withdrawn in view of applicant's amendments to the claims.

With regard toe the scope of enablement rejection, this rejection has been extensively modified to address the amendments to the claims. Nonetheless, applicant's remarks are

addressed insofar as they might be relevant to the instant rejection. Applicants argue at page 8 of the response that given the guidance in the specification it would not require undue experimentation for one to prepare a probe as instantly claimed because that person would be guided by the process described in example 4. However, this is not persuasive for all of the reasons set forth in the modified rejection. Namely, within the scope of the instantly claimed invention, not even SEQ ID NO: 2 appears to actually be "specific" to the P2K6 strain as is implied by the claim. Applicant is reminded that this term is unclear as discussed herein and that the enablement rejection is set forth to address an interpretation of the claim whereby "specific" is meant to require that the probe would detect only the strain recited or that it is "unique" that strain and would not be found in any other stains. The rejection is applied to the amended claims.

New 112 2nd rejections are set forth to address the amendments to the claims.

The 102 rejection in view of Maruyama et al.-1 of claims 2, 4, and 6 is maintained and newly applied to claims 11 and 12. Applicant argues that the reference does not disclose a sequence specific to the P. pacificensis strain NIBH P2K6. This argument is specifically addressed in the rejection.

The rejection of claim 5 under 35 U.S.C. 102(b) as being anticipated by Maruyama et al (Marine Biology 128:705-711 [1997])("Maruyama et al-1") and Bowman et al (Applied and Environmental Microbiology 63(8):3068-3078 [8/1997]) are WITHDRAWN because these do not teach the active process step of "obtaining the purified 16S rDNA of Psychrobacter pacificensis."

The rejection of claims 2, 4, and 6 under Bowman et al. is withdrawn because this rejection is entirely duplicative of the rejection in view of Maruyama et al. with respect to these product claims.

The rejections under 102(a) are withdrawn in view of the perfection of foreign priority.

Conclusion

- Instant SEQ ID NO: 1 is free of the prior art. The closest match to the full length of SEQ ID NO: 1 is given in GenBank U85876, and is the 16S ribosomal RNA gene from P. glacincola. This sequence is 87% identical to instant SEQ ID NO: 1 over the full length of instant SEQ ID NO: 1. An alignment is provided with this office action (Sequence Alignment 1).
- Applicant is advised that should claim 3 be found allowable, claim 10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). These claims are considered to be substantial duplicates of one another because nucleotides 458-476 of SEQ ID NO: 1 are identical to SEQ ID NO: 2.
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Wednesday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, W. Gary Jones can be reached by calling (571) 272-0745.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

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